

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AFFYMETRIX, INC.,

Plaintiff/Counter-
Defendant,

v.

ILLUMINA, INC.,

Defendant/Counter-
Plaintiff.

C.A. No. 04-901-JJF

REDACTED VERSION

**PLAINTIFF AFFYMETRIX, INC.'S STATEMENT OF DISPUTED
MATERIAL FACTS IN RESPONSE TO ILLUMINA, INC.'S
MOTION FOR SUMMARY JUDGMENT OF
UNENFORCEABILITY OF THE '243 PATENT**

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1.

INTRODUCTION

1. Pursuant to this Court's Memorandum Order on Summary Judgment Procedure, Plaintiff Affymetrix, Inc. ("Affymetrix") submits this Counter-Statement certifying that genuine issues of material fact exist and setting forth such disputed facts in opposition to Defendant Illumina, Inc.'s ("Illumina") Motion For Summary Judgment of Inequitable Conduct and Unenforceability of U.S. Patent No. 6,646,243. (D.I. 281, 282.)

2. Illumina claims that its motion presents the most "clear cut" example of its many and varied allegations of inequitable conduct. Examination of that claim recalls the repeated wisdom of the Federal Circuit:

We add one final word: the habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client's interests adequately, perhaps. They get anywhere with the accusation in but a small percentage of the cases, but such charges are not inconsequential on that account. They destroy the respect for one another's integrity, for being fellow members of an honorable profession, that used to make the bar a valuable help to the courts in making a sound disposition of their cases, and to sustain the good name of the bar itself. A patent litigant should be made to feel, therefore, that an unsupported charge of "inequitable conduct in the Patent Office" is a negative contribution to the rightful administration of justice. The charge was formerly known as "fraud on the Patent Office," a more pejorative term, but the change of name does not make the thing itself smell any sweeter. Even after complete testimony the court should find inequitable conduct only if shown by clear and convincing evidence. A summary judgment that a reputable attorney has been guilty of inequitable conduct, over his denials, ought to be, and can properly be, rare indeed.

Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988) (emphasis in original).

2.

3. Inequitable conduct requires proof that material information was concealed from the patent office and that this failure to disclose was the result of an intent to deceive the patent office. *M. Eagles Tool Warehouse, Inc., v. Fisher Tooling Co.*, 439 F.3d 1335, 1339-40 (Fed Cir. 2006). Both intent and materiality must be proved by clear and convincing evidence. *Id.* at 1340. The Federal Circuit “‘urges caution’ in making an inequitable conduct determination at the summary judgment stage.” *Id.* at 1340, 1343 (reversing district court’s grant of summary judgment of inequitable conduct).

4. Illumina’s Motion For Summary Judgment should be denied without further briefing. Unlike most inequitable conduct cases, Illumina has not even proven a failure to disclose information to the USPTO. Disputed issues of fact exist as to (1) whether the subject matter of the ‘243 was involved in any of the prior litigations, (2) if so, whether adequate disclosure occurred, (3) whether the supposedly undisclosed facts are material, and, finally, (4) whether, if disclosure was not sufficient, there was an intent to deceive.

5. Affymetrix was not obligated to disclose its prior litigation in prosecuting the ‘243 patent because the subject matter of the ‘243 patent is distinct. Yet, Affymetrix attempted to provide the examiner with a comprehensive view of all prior litigation in which any Affymetrix patent was asserted. In contrast to Illumina’s characterization of the May 30, 2002 IDS as an exercise in deception, review of the IDS shows that it discloses a complex set of related litigation and administrative proceedings and the prior

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art and enablement attacks disclosed therein in a concise and accessible manner. The May 30, 2002 IDS (Exh. I)¹:

- discloses the nature of the substantive allegations of validity, enablement, and inequitable conduct that had been made against other Affymetrix patents in a variety of forums;
- discloses the main consolidated case number – 3192 – to which both the 4508 and the 4507 litigation were consolidated by order of the District Court and in which the joint claim construction hearing was conducted;
- discloses another litigation docket number – 4508 – to which the 4507 litigation was also related by order of the District Court.
- discloses prior art cited against the patents in pending litigation organized into easily usable CD-ROMs with hyperlinks to the references and a built-in piece of software to enable Boolean searching across all references; and
- discloses at least three different places where either the Pirrung declaration itself, or other related declarations based on Pirrung's publications, were available – including on the internet from the European Patent Office.

While one can always do something more perfectly in 20/20 hindsight, the IDS demonstrates a substantial and effective disclosure of the substantive issues and prior art raised in a complicated series of overlapping litigation and administrative proceedings.

6. Furthermore, there are factual disputes regarding whether the allegedly concealed facts are material. On two occasions, the USPTO considered whether the publications and substantive arguments of Dr. Pirrung undermined the enablement of two other Affymetrix patents, the '305 and '992. On both occasions, the USPTO found that Dr. Pirrung's work – despite pointing out potential problems in commercial implementation of certain techniques of the invention – in fact *supported* a finding of enablement. As to the 4507 litigation, Illumina relies entirely on a supposed *per se*

¹ All citations to *lettered* exhibits refer to Illumina's exhibits to their opening brief. All citations to *numbered* exhibits refer to exhibits attached hereto.

4.

standard of materiality for failure to disclose litigation. But, of course, no such failure occurred, as both the lead consolidating case and another related case were disclosed, either of which includes numerous references to the third docket. Illumina fails to show materiality as to the 4507 litigation beyond this *per se* theory.²

7. Similarly, the allegedly concealed facts were not only *not* material, they were also cumulative of other disclosures made to the USPTO.

8. Finally, *even if*—despite the extensive disclosure outlined above—the IDS was found not to disclose adequately either the Pirrung declaration or the 4507 litigation; and *even if* these facts were found to be material and not cumulative; there remains a factual dispute as to whether there was an intent to deceive. This dispute exists due to the facts and circumstances themselves, but is confirmed by the declaration of Mr. McGarrigle, a well-respected, long-time practitioner before the USPTO, explaining that he had no such intent.

ARGUMENT

I. AFFYMETRIX WAS NOT OBLIGATED TO DISCLOSE THE 4507 OR ANY OF THE OTHER LITIGATION BECAUSE THE SUBJECT MATTER OF THE '243 PATENT WAS NOT INVOLVED IN ANY OF THESE LITIGATION.

9. The Manual of Patent Examining Procedure (“MPEP”) states that “[w]here the subject matter for which a patent is being sought is or has been involved in

² Recent discussions of MPEP 2001.6(c) do not agree that a *per se* rule applies. See, e.g., *Kothmann Enters., Inc. v. Trinity Indus., Inc.*, 2006 WL 89838, at *13-14 (S.D. Tex. January 13, 2006) (“Neither the district court nor the Federal Circuit simply equated the failure to disclose the existence of related litigation or specific materials from that litigation to a breach of the disclosure duty.”)

5.

litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office.” MPEP § 2001.06(c) (emphasis added). Illumina argues that because the ‘243 has ancestor patents in litigation with similar specifications, this created a *per se* obligation to disclose the litigation of these other patents. But this argument expands the obligation to disclose litigation beyond that intended by the MPEP. *See, e.g., Kothmann Enters.*, 2006 WL 89838, at *13-14 (“In applying the MPEP, the [Federal Circuit] did not merely examine whether the patent-in-suit and the patent-in-prosecution involved similar claimed inventions, but specifically analyzed the claim terms at issue in both the litigation and the patent prosecution to see whether and how the litigation affected the patentability of the invention claimed in the application.”)

10. First, the *subject matter* of the ‘243 patent was not involved in any of the litigations at issue as required for MPEP § 2001.06(c) to apply. Although the ‘243 and ‘934 patents are derived from a common source and they share the same specification, they claim independent and distinct inventions. The ‘243 patent is a divisional, and not a continuation, of the ‘934 patent. A divisional application is defined in the MPEP as follows:

A later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or “division.”

MPEP § 201.06 (emphasis added). The ‘243 patent is a grandchild of U.S. Patent No. 6,225,625, which is a divisional of the ‘934 patent. The application that culminated in the ‘625 patent was filed in response to a restriction requirement from the PTO issued during the prosecution of a predecessor application to the ‘934 patent. *See* 35 U.S.C. §

6.

121 (“If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.”). In fact, during prosecution of the predecessor application to the ’934 patent, the Examiner determined that the proposed claims were directed to at least two independent and distinct inventions, resulting in the filing of the divisional application that resulted in the ’625 patent. As such, the ’625 patent and all the continuations stemming therefrom, including the ’243 patent, claim subject matter independent and distinct from the ’934 patent.³ Thus, MPEP § 2001.06(c) either does not apply, or there is a disputed issue of fact as to whether it does.

II. **THERE ARE DISPUTED FACTS AS TO WHETHER THERE WAS A FAILURE TO DISCLOSE.**

11. In most cases alleging inequitable conduct, one thing is not disputed: The applicant was aware of some piece of information *and failed to disclose it*. But here, even the simple fact of whether there was a failure to disclose is disputed.

12. Illumina accuses Affymetrix of intentionally withholding from the patent office two things: (1) the fact of the 4507 litigation, and (2) the fact that Dr. Pirrung, a named inventor on the ’243 patent, had submitted a declaration regarding the ’992 patent – a declaration that Illumina and others mistakenly assert supports a lack of enablement.

³ “Plain common sense dictates that a divisional application filed as a result of a restriction requirement may not contain claims drawn to the invention set forth in the claims elected and prosecuted to patent in the parent application. The divisional application must have claims drawn only to the ‘other invention.’” *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 687 (Fed. Cir. 1990) (citation omitted).

7.

However, Illumina has failed to prove the most basic tenet of an inequitable conduct allegation, because both of these facts effectively were disclosed to the Patent Office.

**A. ILLUMINA MAKES MISTAKES IN
DESCRIBING THE LITIGATION TO THIS
COURT.**

13. Demonstrating the challenges of accurately describing the inter-related litigations, Illumina fails in its brief at pages 4 and 5 to describe the litigations correctly, even while accusing others of fraud for similar mistakes. Presumably, Illumina's inaccurate description of the related litigations to this Court is not a violation of their duty of candor and reasonable inquiry pursuant to Rule 11, but rather the result of simple, honest mistakes.

14. Illumina states that "Affymetrix filed two patent infringement actions in 1998." (Illumina Br. at 4.) This is a mistake.

15. Affymetrix filed three patent infringement lawsuits in 1998, as is readily apparent from the one page summary offered at Exhibit C (the exhibit relied upon by Illumina). Two lawsuits were filed against Incyte and Synteni in Delaware in January and September. They bore the numbers 98cv6 and 98cv520. (Exh. B and E.) These cases were related and later transferred to the Northern District of California where they were renumbered consecutively as 98cv4507 and 98cv4508. (Exh. F and G.) The third case was filed against Hyseq in the Northern District of California in September 1998. It bore the case number 98cv3182, but Illumina did not include this docket. (See Exh. 1 at D.I. 1-160 (reflecting the original 3182 number).) Upon transfer of the Delaware cases to the Northern District of California, Affymetrix immediately filed a notice of related cases, and the first action of the Northern District was to consolidate them with the 3182

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docket. (See Exh. G (4508 docket) at D.I. 3 (Affymetrix notice) and 10 (Judge Smith's order; *see also* Exh. F (4507 docket) at D.I. 4 (Judge Smith's order).)⁴

16. Illumina states that in the 4508 case: "Affymetrix alleged infringement of U.S. Patent No. 5,800,992 ("the '992 patent"), U.S. Patent No. 5,744,305 ("the '305 patent") and U.S. Patent No. 5,795,716 ("the '716 patent')." (Illumina Br., at 4.) This, too, is a mistake.

17. As is apparent from Illumina's Exhibit C, the '305 and '992 patents were asserted in the 4508 case versus Incyte and Synteni, but the '716 patent was not. The '716 patent was only asserted against Hyseq in the 3182 litigation. (Exh. C.)

18. Illumina states that the the 4508 case "ceased to exist as a separate case beyond that point [*i.e.*, the April 8, 1999 consolidation order]." (Illumina Br. at 4-5.) This is another mistake.

19. Most simply, the 4508 docket exhibited to Illumina's brief shows that filing continued in the 4508 case after April 8, 1999. (See Exh. G, D.I. 186-205 (docket entries dated from April 9, 1999, through September 14, 1999).) But even this is not the entire story. As described above, in December, shortly after the two related Delaware cases were transferred to the Northern District, Judge Smith consolidated all three cases. (See, *e.g.*, Exh. G at D.I. 10.) In August 1999, the cases were reassigned to Judge

⁴ The December 14, 1998 docket entry in both the 4507 and 4508 cases reads as follows: "ORDER by Judge Fern M. Smith relating case C-98-3192-FMS with member cases C-98-4507-JL and C-98-4508-DLJ; Case reassigned to Judge Fern M. Smith." Exh. F at D.I. 4; Exh. G at D.I. 10. In an example of the sometimes unusual occurrences in these related matters, the 3192 docket (Exh. 1) does not reflect Judge Smith's order and Hyseq, the defendant in the 3192 case apparently was not served with notice or the order. (See Exh. 1 at D.I. 41 (defendant never received notice of related cases file and does oppose relating the cases).)

9.

William Alsup. (Exh. F. at D.I. 79; Exh. G at D.I. 201.) After consulting with the parties, Judge Alsup ordered a joint *Markman* hearing in all three cases. (See, e.g., Exh. F at D.I. 94.) In December 1999, Judge Alsup recused himself due to connections with his former firm. (Exh. F at D.I. 103; Exh. 1 at D.I. 153.) All three cases were then transferred to Judge Fogel in the San Jose Division of the Court. (See, e.g., Exh. H at D.I. 104.) At that time the cases were renumbered with three consecutive numbers, 21163 (formerly 3192), 21164 (formerly 4507), and 21165 (formerly 4508). Illumina provided only one of these dockets, 21164, as Exhibit H. Illumina did not exhibit the 21163 docket or the 21165 docket to its brief. (See Exh. 1 (21163 docket) and Exh. 2 (21165 docket).) Despite the related case and consolidation orders (and despite Illumina's mistaken representation to the contrary), all three dockets remained open and, as discussed below, the attorneys, the Clerk of the Court, and even the Honorable District Court Judges continued to make mistakes when referencing or filing documents in the case.⁵

20. As revealed by this discussion and Illumina's confusion in its brief, these litigations were overlapping, related, and difficult to separate. Here is a summary for the court's assistance:

- *Affymetrix, Inc., v. Hyseq, Inc.*, was filed in the Northern District of California on August 18, 1998, and given the docket number **98cv3192** FMS. The '305, '992, and '716 patents were asserted in this litigation. Upon reassignment of the case to Judge Fogel, Northern District of California (San Jose Division), the case was renumbered as **99cv21163**. (See Exhibit 1 for 21163 docket, which includes the entries from 3192.)

⁵ Furthermore, there are several additional cases in this time frame between Affymetrix, Hyseq, and Incyte which are occasionally referenced in the different dockets. None of those appear to be relevant here, so they are not exhibited or discussed.

10.

- *Affymetrix, Inc., v. Synteni, Inc. and Incyte Pharmaceuticals, Inc.*, was filed in Delaware on January 6, 1998, and given the docket number **98cv6 GMS**. The '934 patent was asserted in this litigation. Upon transfer to the Northern District of California (San Francisco Division), the case was renumbered as **98cv4507**. Upon reassignment of the case to Judge Fogel, Northern District of California (San Jose Division), the case was renumbered as **99cv21164**. (See Exhibit H for 21164 docket, which includes the entries from 4507.)
- *Affymetrix, Inc., v. Synteni, Inc. and Incyte Pharmaceuticals, Inc.*, was filed in Delaware on September 1, 1998, and given the docket number **98cv520 JJF**. It was later reassigned to GMS. The '305 and '992 patents were asserted in this litigation. Upon transfer to the Northern District of California (San Francisco Division), the case was renumbered as **98cv4508**. Upon reassignment of the case to Judge Fogel, Northern District of California (San Jose Division), the case was renumbered as **99cv21165**. (See Exhibit 2 for 21165 docket, which includes the entries from 4508.)

**B. THE MAY 30, 2002 IDS DISCLOSES THE
EXTENSIVE LITIGATION PROCEEDINGS
REGARDING OTHER AFFYMETRIX
PATENTS INCLUDING, EFFECTIVELY, THE
4507 LITIGATION.**

21. Despite lacking any obligation to do so, as discussed *supra* Section II, Affymetrix made a good faith effort to disclose *all litigation involving its patents* whether related to the subject matter of the pending application or not. In its May 30, 2002 IDS, Affymetrix disclosed the lead case number under which all related litigation was consolidated by the District Court of the Northern District of California – “*Affymetrix, Inc. v. Hyseq, Inc.*, US District Court for the Northern District of California, San Francisco Division, Civil Action No. C98-03192 FMS.” (Exh. I at 3.) Indeed, immediately upon transfer of the Delaware-venued Incyte cases to the Northern District in November 1998, Affymetrix filed a notice of related cases relating 3192, 4507, and 4508. (Exh. G at D.I. 3). Shortly thereafter, on December 14, 1998, the District Court in the Northern District of California consolidated all three cases. (Exh. G at D.I. 10.); *see*

11.

also Exh. F at D.I. 4 (same).) The May 30, 2002 IDS also discloses the litigation against Incyte, but named only one of the two related dockets: “*Affymetrix Inc., v. Synteni Inc., and Incyte Pharmaceuticals, Inc.*, US District Court for the Northern District of California, San Francisco, Case No. C98-4508 FMS (MEJ).” Finally, the IDS discloses another lawsuit in which Affymetrix had attempted to file counter-claims alleging infringement of its patents: “*Incyte Genomics Inc. v. Affymetrix*, U.S. District Court, Northern [D]istrict of California San Francisco [D]ivision and is Case No. C 00-3210 JF.” (Exh. I at 3.) Until the instant lawsuit was filed against Illumina in 2004, this was the entire universe of patent litigation in which Affymetrix had asserted its patents.

22. Illumina correctly points out that one of three docket numbers in these related litigations was omitted from the May 30, 2002 IDS: The 4507 docket number. But the fact that this docket number was omitted – while not perfect in hindsight – does not undermine the substantial effort to disclose all litigation where any of Affymetrix’s patents had been asserted. Because the cases were related and consolidated, a cursory review of either the 3192 docket or the 4508 docket would have quickly revealed the existence of the 4507 docket. Likewise, a review of, for instance, the *Markman* order – obviously one of the most important documents in any patent litigation – would have explicitly discussed in detail all of the patents-in-suit across all three cases. (See Exh. 3.)

23. Discussion of the related cases appears in a variety of places in the 3192 docket including, most notably, in the joint claim construction proceedings held for all three docket numbers. For example, in the summer of 1999, the case was reassigned from Judge Smith to Judge Alsup. Judge Alsup promptly set a schedule for technology tutorial and claim construction and sought guidance from the parties with regard to

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whether to consolidate claim construction proceedings – explicitly mentioning the 4507 case:

Parties are to submit written statements on whether: (1) the claim construction hearings should be consolidated; and (2) whether the parties to Affymetrix Inc. -v- Hyseq Inc., C98-3192 should participate in the technology tutorial scheduled in Affymetrix Inc. -v- Synteni Inc., C98-4507.

(Exh. 1 at D.I. 119).⁶ (*See also* Exh. 1 at D.I. 125, 134, 147, 148, and 150 (for additional cross references to 4507); Exh. 1 at D.I. 265 and 270 (for references to patents-in-suit ‘934, ‘305, ‘992, and ‘716).) Then, the claim construction proceeding for all three dockets was conducted and docketed solely in the 3192 docket. (*See* Exh. 1 at D.I. 197 to 256 (almost 60 docket entries re: claim construction from October 2000 to March 2001) compared to Exh. H at D.I. 262 to 263 (no claim construction entries or any entries at all for most of January, February, and March); and Exh. 2 at D.I. 230 to 231 (no activity from November 2000 to March 2001, and no reference to the claim construction proceedings).)

24. Furthermore, each of the patents-in-suit across the three proceedings – including the ‘934 patent – is mentioned in several of these 3192 docket entries. (Exh. 1 at D.I. 242 (“ORDER construing claims of U.S. Patents nos. 5,445,934, 5,744,305, 5,800,992, and 5,795,716 by Judge Jeremy Fogel.”); *see also* Exh. 1 at D.I. 254, 255, 256 (mentioning ‘934 patent as well as other patents).) The *Markman* order itself, filed at D.I. 242 in the 3192 docket, contains an entire section on the ‘934 patent. (Exh. 3, Order Construing Claims of U.S. Patents Nos. 5,445,934, 5,744,305, 5,800,992, and 5,795,716,

⁶ The District Court omitted mention of the 4508 docket which had also previously been related.

13.

at 8-16.) In fact, while this *Markman* order applied to all three dockets and four patents-in-suit across those three dockets, this is the only docket in which it appears. Of note, the *Markman* order groups the '934 and '305 patents and notes similarities between the two in its discussion. (See Exh. 3 at 2:11-12; 3:5.)

25. The District Court caption and the order itself include an error in referencing the docket numbers. On its face page, the order references the 21163 docket (the successor number to the 3192 docket) and the 21164 docket (the successor to the 4507 docket), but omits reference to the 4508 docket (or its successor 21165 number). (Exh. 3.) In the body of the order the Court states: "*In the two cases captioned above [21163 and 21164], Affymetrix asserts that Defendants Incyte Pharmaceuticals, Inc. and Synteni (collectively, "Incyte") infringe the '934, '305, and '992 patents; and that Defendant Hyseq, Inc. ("Hyseq") infringes the '305, '992, and '716 patents.*" (Exh. 3 at 2:19-21.) This is a mistake. In fact, the '305 and '992 patents were only asserted against Incyte in the 4508/21165 case.

26. Anyone reviewing either the 4508 docket or the 3192 docket – both of which were disclosed in the IDS – would immediately learn (1) that there was another related docket number (4507) and (2) that there were two additional patents in suit (the '934 in the 4507 case and the '716 in the 3192 case). In fact, the *Markman* order describes in great detail all of the patents-in-suit and also discusses the 4507 docket. Thus, there is a factual dispute about whether Affymetrix effectively did disclose the 4507 litigation by referencing the two related dockets, including the lead 3192 docket.

14.

**C. THE MAY 30, 2002 IDS DISCLOSES THE
SUBSTANCE OF THE ALLEGATIONS
AGAINST OTHER AFFYMETRIX PATENTS
ARISING IN LITIGATION AND
ADMINISTRATIVE PROCEEDINGS.**

27. In its May 30, 2002 IDS, Affymetrix informs the examiner generally that there is a variety of litigation and administrative proceedings in which allegations of invalidity have been raised. First, it listed two interferences in which the '305 and '992 patents were challenged "on the basis of lack of enablement and written description under 35 U.S.C. § 112, among other issues," and identifies the main paper summarizing the arguments. (Exh. I at 2-3.) Second, it listed two of three litigation docket numbers related to litigation against Hyseq and Incyte and stated: "In the course of these proceedings, allegations of invalidity over prior art, lack of enablement, lack of support and inequitable conduct (relating to duty of candor, content of declarations under 37 CR [sic] §1.132, and arguments made during prosecution) were raised." (Exh. I at 3.) Third, the IDS listed a European Opposition relating to the European equivalent of the '934 patent. (Exh. I at 3.) Fourth, the IDS also notes other litigation and administrative proceedings that might be of interest to the examiner. (Exh. I at 3-4.) Finally, the IDS offers to provide copies of litigation documents that may be of interest.

28. All of this is in substantial compliance with the suggestion of the MPEP. In contrast to the patentee in *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp. 2d 508, 551 (D.N.J. 1999), Affymetrix did disclose "the name of the pending case, its docket number, the district in which it was pending" as well as the fact that the litigations were settled and a summary of the substance of the allegations relating to validity. *Id.* Affymetrix also offered to provide any documents from any of these cases that were of interest to the examiner. Thus, there is a disputed issue of fact whether

15.

the IDS discloses the litigation of Affymetrix patents regardless of whether those patents are of the same subject matter.

D. THE MAY 30, 2002 IDS DISCLOSES PRIOR ART CITED IN THESE VARIOUS DIFFERENT PROCEEDINGS IN A WELL-ORGANIZED AND SEARCHABLE CD-ROM.

29. In addition to this overview of the related litigation and administrative proceedings, the IDS seeks to provide the patent office with easy access to prior art cited in any of these proceedings.

30. In an attempt to organize all of this voluminous material in a readily accessible fashion, Affymetrix took extra efforts beyond anything suggested, for example, in the MPEP. Hard copies of references were provided in binders (which were occasionally updated). The binder set was provided to key supervising examiners for central access. (Exh. I at 1-2; Declaration of Phillip L. McGarrigle (herinafter “McGarrigle Decl.”) at ¶ 20.)

31. In addition to these binders, Affymetrix created CD-ROMs with both PDF and TIFF copies of the references. (Exh. I at 1-2; McGarrigle Decl. at ¶¶ 20-21.) Affymetrix engaged a vendor to provide software on each CD that would allow the examiners to run Boolean word searches across all the references to try to find the most pertinent references. The organization of the CD is described both in the IDS and in the “ReadMe.HTML” file contained on the CD. A printout of this file is attached hereto as Exhibit 4. As stated therein, the software included on the CD:

Provides a wide range of searching capabilities, and allows full Boolean searching with proximity connectors and other useful features found in modern search programs.

(Exh. 4 at 2.)

16.

32. The 1449 form – which also serves as the index for the CD-ROM – includes 21 pages linked to more than 600 references cited against the patents in various proceedings. With a handful of exceptions, the 600 references include all the references cited against the '934 patent in the 4507 litigation. Because of the large volume of references opponents were citing in these various proceedings, Affymetrix undertook this effort to make the references easily accessible in multiple formats and provided a built-in search function for examiners to narrow their consideration to the most relevant references. (McGarrigle Decl. at ¶ 22.) Affymetrix consulted with the USPTO during this process and received their approval for submission in this format. (McGarrigle Decl. at ¶ 20.)⁷

33. Again, these facts suggest substantial compliance with the requirements of the MPEP. Accordingly, there is a factual dispute about whether disclosure was, in fact, made.

**E. THE DISCLOSURE OF THE 4508
LITIGATION EFFECTIVELY DISCLOSES
THE INEQUITABLE CONDUCT
ALLEGATIONS FILED IN THE 4507
AMENDED COMPLAINT.**

34. Other than relying on a supposed *per se* violation, the only substantive “non-disclosure” of litigation asserted by Illumina is as follows:

By failing to disclose the existence of the 4507 litigation, Affymetrix was able to conceal from the examiner, *inter alia*, the invalidity and inequitable conduct allegations that were made by Incyte and Synteni in the 4507 litigation.

⁷ Because this conversation was about this general issue and not a particular patent application, there may not be a record of the conversation in any one patent file.

(Illumina Br. at 16.) Illumina provides two concrete examples: (1) Incyte's Initial Disclosure of Prior Art (Exh. M), and (2) Incyte's pleadings regarding inequitable conduct. In making these allegations, however, Illumina fails to disclose to this Court that the documents in the 4507 case – which Affymetrix allegedly intentionally hid from the PTO – were *nearly identical* to the versions of these documents in the 4508 case, the existence of which Affymetrix did disclose.

35. Illumina has access to the Initial Disclosure of Prior Art filed in both the 4507 and 4508 cases,⁸ yet Illumina provided only a copy of the former (Exh. M) and not the latter (Exh. 5 and 6). Side-by-side comparison of Exhibit M (from the 4507) with Exhibit 5 (from the 4508) show that they are *almost exactly identical*. Likewise, as discussed above, Affymetrix provided art cited in these filings in both hard copy and in a searchable CD-ROM format. Thus, there is a disputed fact whether these documents were effectively disclosed to the PTO.

36. The situation is similar with regard to the inequitable conduct allegations made – but never proven – by Incyte and Synteni. Upon recent request to counsel at Irell & Manella, copies of the proposed amended complaints with new allegations regarding inequitable conduct that Illumina appears to refer to in footnote 8 were provided to Affymetrix. (See Exh. 7 and 8.)⁹ Comparison of the amended complaint filed in the

⁸ Illumina obtained Exhibit M from the file history of another patent application. In that file history, one of Affymetrix's outside patent counsel filed all the Initial Disclosures filed in the 4507, 4508 and 3192 cases, as Illumina noted. (See Exh. L.)

⁹ Irell satisfied itself that these documents contained only Affymetrix confidential information before providing them to Affymetrix and has received no objection from Incyte's counsel to providing them to Affymetrix (or the Court).

18.

4507/21164 case (Exh. 7) (which Affymetrix allegedly tried to hide) and the amended complaint filed in the 4508/21165 case (Exh. 8) (which litigation Affymetrix explicitly referenced) shows that the vast majority of inequitable conduct allegations in the 4507 complaint are repeated *verbatim* in the 4508 complaint. (*Compare* paragraphs 34-55 in the 4507 complaint (Exh. 7) *with* paragraphs 64 to 85 in the 4508 complaint (Exh. 8).)

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Exh. 7.)

Exh.

8). Thus, there is a disputed issue of fact regarding whether the details of these unproven allegations of inequitable conduct were effectively disclosed to the PTO by the explicit reference to the 4508 litigation and an offer to provide any documents of interest to the examiner.

F. THE MAY 30, 2002 IDS DISCLOSES AT LEAST TWO SEPARATE PLACES WHERE THE PIRRUNG DECLARATION WAS AVAILABLE, AND ANOTHER PLACE WHERE A SUBSTANTIVELY SIMILAR DECLARATION WAS FILED.

37. As discussed in more detail below, the Pirrung declaration only specifically mentions the '992 patent and is concerned largely with issues of commercial implementation of the photolithographic synthesis technique. Despite its lack of relevance to the '243 patent, Illumina accuses Affymetrix of withholding the Pirrung declaration from the Patent Office. However, there are disputed facts as to whether the declaration was effectively disclosed because the May 30, 2002 IDS directed the

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examiner to two different places where the declaration was available, including on-line, as well as a third location where similar arguments based on Pirrung's publications were considered and rejected by the PTO.

38. As discussed above, the IDS explicitly references the 4508 docket. As Illumina concedes, the Pirrung declaration was filed in the 4508 docket. (Exh. G at D.I. 130.)

39. Illumina fails to disclose to this Court that the Pirrung declaration was also filed in the European Patent Office. Nor does Illumina mention that the opposition proceedings in which the declaration was filed are specifically described in the IDS: "Further, oppositions have been filed against a related European application EP 619,321 in the European Patent Office." (Exh. I at 3.) In fact, the version of the Pirrung declaration submitted by Illumina is the version from the European Patent Office file as determined by the unique date markings on the top of each page. (McGarrigle Decl. at ¶ 27.) The proceedings of the European Patent Office – including the Pirrung declaration – were then and are today available on-line to the public (and, obviously, to patent examiners).

40. Finally, the IDS explicitly references two different interference proceedings before the USPTO aimed at the validity of the '305 and '992 patents. In both of these interferences, Incyte based a major aspect of their challenge to the patents on the same enablement theory articulated in Dr. Pirrung's declaration. Specifically, Incyte filed a declaration from Dr. Larry Kricka, which made similar arguments to those made in Dr. Pirrung's declaration and was largely based on Dr. Pirrung's publications.

20.

(Compare Exh. 9, Kricka Declaration, with Exh. N, Pirrung declaration.) The papers filed in these interference proceedings were available to examiners for their review.¹⁰

41. Again, where the examiner was told that opponents had challenged the enablement of other Affymetrix patents, and where the examiner was provided multiple locations where documents related to that challenge could be found, there are disputed issues of fact regarding whether Affymetrix made effective disclosure of the Pirrung declaration.

**III. THERE ARE ALSO DISPUTED FACTS AS TO
WHETHER THESE SUPPOSEDLY NON-
DISCLOSED FACTS ARE MATERIAL.**

42. For information to be material, it must not be cumulative of information already in the record and it must establish by itself or in combination with other information a *prima facie* case of unpatentability or refute a position taken by the applicant in arguing for patentability. *Purdue Pharma, L.P., v. Endo Pharm., Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006) (citing and discussing PTO Rule 56). For numerous reasons outlined below, there are disputed issues of fact as to whether the allegedly withheld information was material.

¹⁰ Within the time frame of 2002 to present, the interference file for the '305 and '992 patents would have been publicly accessible and accessible to examiners, because (1) the interference involved a patent, (2) the interference was terminated, and (3) an award of priority or judgment had been entered as to all parties and all counts. (See Exh. 10 and 11.) Under these conditions, the file of the interference is open to inspection by the public. See 37 C.F.R. § 1.11(e) and 35 U.S.C. § 122.

**A. THERE ARE SEVERAL FACTUAL
DISPUTES REGARDING WHETHER THE
PIRRUNG DECLARATION IS MATERIAL.**

**1. The USPTO Had Already Twice Rejected
The Substance Of The Pirrung
Arguments Regarding Enablement In
August 1999.**

43. In two different interferences attacking the validity of the '305 and '992 patents, Incyte and Synteni submitted both the Pirrung declaration and a declaration from Dr. Kricka discussing Pirrung publications and argued that Affymetrix's patents were not enabled. Recall that the Pirrung declaration – whose arguments were summarized by Dr. Kricka in the interference – was specifically directed to the '992 patent. (Exh. N.)

44. In both interferences, the Administrative Patent Judges Smith, Schafer, and Torczon found that, in fact, Pirrung's work *supported* enablement. In particular, they found that a 1995 article discussing problems with light-directed, solid-phase DNA synthesis supported enablement:

Perfection or optimization of an invention, however is not a requirement of enablement. [Cite omitted.] Nowhere does Pirrung state that the light-directed method of synthesis will not work. In fact, Pirrung states that light-directed synthesis is advantageous for preparing large, high-density arrays of polymer sequences to enable sequencing-by-hybridization.

(Exh. 10 at 10; Exh. 11 at 11.) In both cases, the Board of Patent Appeals concluded that Brown/Incyte (relying primarily on Dr. Kricka's discussion of Pirrung's articles) had "failed to establish a threshold case by a preponderance of the evidence that Fodor's disclosure would not have enabled one skilled in the pertinent art to make and use the claimed invention." (Exh. 10 at 11; Exh. 11 at 11.)

45. Thus, where the USPTO has twice considered and rejected the substance of the non-enablement arguments based on Dr. Pirrung's work detailing some difficulties of light-directed synthesis, it can hardly be said to be material. Of note, the District Court denied motions for summary judgment on the same issue pending the outcome of these interferences. (Exh. 2 at D.I. 198.) (Nevertheless, Affymetrix continued to disclose that enablement attacks had been made.) In any case, there is a factual dispute as to the materiality of the Pirrung declaration.¹¹

**2. The Pirrung Declaration Concerns A
Different Patent.**

46. Illumina argues that the Pirrung declaration was material to the patentability of the '243 patent because the declaration states that the VLSIPS method addressed in the '992 patent could not be used to make nucleic acid arrays as of the 1990 time frame. The claimed subject matter of the '243 patent, however, is not directed to the VLSIPS method or a method used to make nucleic arrays. Rather, the claims of '243 patent are directed toward an apparatus and method of analyzing polynucleotide and nucleic acid binding, while the claims of the '992 are directed toward a method of detecting nucleic acid in two or more collections of nucleic acid sequences and a method of detecting differential expression in genes.

¹¹ Dr. Anne Pease, a post-doctoral student without any special training in synthetic chemistry and no experience with photochemistry, joined Affymax in late 1990. She was assigned to manufacture oligonucleotide arrays using VLSIPS.

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47. Therefore, the '243 patent is not directed toward the same subject matter and does not claim the same invention as the '992 patent. Even if Pirrung's declaration would be considered material to the invention claimed in the '992 patent, it is not material to the distinct invention claimed in the '243 patent. *See Environs Prods., Inc. v. Total Containment, Inc.*, 1997 WL 364464 at *5 (E.D. Pa. June 19, 1997) (noting that certain information might be material to one application, while immaterial to a related application that does not claim the same invention). In any case, there is certainly a disputed fact regarding materiality.

**B. THE MERE EXISTENCE OF THE 4507
LITIGATION IS NOT MATERIAL.**

48. Illumina contends that "as the 4507 litigation involved *the basic subject matter* of the '243 patent, the existence of the 4507 litigation was material *per se* to the patentability of the '243 patent." (Illumina Br. at 15 (emphasis added).) Illumina neglects to mention that the '243 patent claims an independent and distinct invention, and thus a distinct subject matter, from the '934 patent. As such, information which may have been material to the '934 patent is not necessarily – and this case is not – material to the '243 patent.

49. As described in more detail above, *supra* Section II, although the '243 and '934 patents are derived from a common source and share the same specification, they claim independent and distinct inventions. The subject matter at issue in the 4507 litigation pertaining to the '934 patent is directed toward an array of oligonucleotides. In contrast, the claims of the '243 patent are directed toward an apparatus and method of analyzing polynucleotide and nucleic acid binding. During prosecution, restriction requirements determined these to be separately patentable inventions. Information

24.

related to an oligonucleotide array would not establish a *prima facie* case of unpatentability of a claim directed to an apparatus and method of analyzing polynucleotides and nucleic acid binding. *See* 37 C.F.R. § 1.56(b). Thus, whether the existence of litigation involving the subject matter of the '934 patent claims is material to the claims of the '243 patent presents a genuine issue of material fact.

**C. FURTHER DISCLOSURE OF THE 4507
LITIGATION WOULD BE CUMULATIVE.**

50. The May 30, 2002 IDS disclosed the lead case number in the consolidated litigation as well as another of the ancillary case numbers. The initial disclosure of prior art in the 4507 litigation (Exh. M.) is a nearly identical copy to the disclosures in the 4508 litigation (Exh. 5.). With a handful of exceptions – none of which Illumina finds pertinent to the '243 – all of the prior art cited in Exhibit M is found on the face of the '243 patent. Disclosure of yet another identical document citing this same art – in a substantially less user-friendly form – would be cumulative. Likewise, the allegations of inequitable conduct contained in the 4507 litigation – which Illumina hints about in footnote 8 – are almost exactly duplicated in the 4508 amended complaint. Accordingly, access to the amended complaint (and related pleadings) in the 4507 case would be cumulative.

51. Thus, there is a disputed issue of fact regarding whether additional disclosure related to the 4507 litigation would have been cumulative.

**IV. THERE ARE DISPUTED FACTS AS TO WHETHER
THERE WAS AN INTENT TO DECEIVE THE
USPTO.**

52. “It is important to remember that materiality does not presume intent, which is a separate and essential component of inequitable conduct.” *Purdue Pharma*, 483 F.3d at 1134 (internal quotes and citations omitted). “Intent to deceive should be determined in light of the realities of patent practice and not as a matter of strict liability....” *M. Eagles*, 439 F.3d at 1343 (“Even if there were evidence of gross negligence in nondisclosure, which was not found, that would not necessarily constitute inequitable conduct.”). “A *summary judgment* that a reputable attorney has been guilty of inequitable conduct, over his denials, ought to be, and can properly be, rare indeed.” *Burlington Indus*, 849 F.2d at 1422 (emphasis in the original).

53. Given that the facts and circumstances described above create a dispute as to (1) whether there was, in fact, even any concealment and (2) whether the supposedly concealed facts are *material*, the inference of intent never arises.

54. Nevertheless, Mr. McGarrigle has submitted a declaration stating what the facts and circumstances make abundantly obvious: that he never intended to deceive the Patent Office. Mr. McGarrigle is a patent attorney with over 20 years of practice before the USPTO for several different clients. (McGarrigle Decl. at ¶¶ 10-14.)

55. Contrary to Illumina’s loosely-constructed allegations of professional misconduct,¹² Mr. McGarrigle and Affymetrix exceeded the duty of disclosure imposed by the letter and spirit of the rules by disclosing the litigation where any of Affymetrix’s

¹² Illumina characterizes this as the most “clear cut” of all of its varied allegations of inequitable conduct against all five of the patents-in-suit. (Illumina Br. at 1.)

26.

patents have been asserted – even though the subject matter of the ‘243 patent was not at issue in those litigations. Affymetrix sought to disclose the complicated litigation and administrative proceedings to the USPTO and make all relevant information readily available to the examiners. The fact that this IDS, in perfect hindsight, could have been even more detailed and even more documents could have been provided to the examiner does not change the fact that it was a substantial effort to disclose everything that might be relevant without, at the same time, overwhelming the examiner. As Illumina itself shows in its brief, honest mistakes or omissions may occur.

56. Thus, there are disputed issues of fact regarding whether Mr. McGarrigle or Affymetrix had an intent to deceive the PTO.

CONCLUSION

Factual disputes exist as to (1) whether the subject matter of the '243 was involved in any of the prior litigations, (2) if so, whether adequate disclosure occurred, (3) whether the supposedly undisclosed facts are material, and, finally, (4) whether, if disclosure was not sufficient, there was an intent to conceal. Therefore, Illumina's motion for summary judgment on this "clear cut" case of inequitable conduct should be denied without further briefing pursuant to this Court's Memorandum Order.

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